

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

[PROPOSED] CLAIM CONSTRUCTION ORDER

WHEREAS, pursuant to the Scheduling Order (D.I. 206), Plaintiff Vanda Pharmaceuticals Inc. and Defendants Teva Pharmaceuticals USA, Inc., Apotex Inc., Apotex Corp., MSN Pharmaceuticals Inc., and MSN Laboratories Private Limited have exchanged proposed claim constructions and intrinsic evidence in support of the proposed claim constructions for U.S. Patent Nos. 10,610,510, 10,610,511, 10,829,465, and 10,611,744; and

WHEREAS, the parties have reached agreement regarding the claim constructions of the terms identified during the exchanges.

NOW, THEREFORE, having considered the constructions agreed upon by the parties, the Court adopts the following constructions:

CLAIM TERM	CONSTRUCTION
U.S. Patent No. 10,610,510, claims 1 and 6; U.S. Patent No. 10,610,511, claims 1, 12, and 18:	The preambles are limiting. ¹
Claim preambles	

¹ See D.I. 105 at 2 (concluding that the preambles in the earlier-asserted method-of-treatment patents are limiting). **Defendants' Position:** Defendants accept that the Court's determination in this regard is the law of the case and applies equally to the preambles of the '510 and '511 patents at issue here. Defendants reserve their rights to appeal that determination with respect to all asserted method-of-treatment patents at the appropriate time if necessary. **Vanda's Position:** Defendants have not preserved any right to appeal or otherwise challenge whether the claim preambles of U.S. Patent Nos. 10,376,487 and 10,449,176 are limiting. In lieu of presenting a dispute to the Court in *Markman* proceedings, those constructions were agreed to by the parties by stipulation (D.I. 183, at 3) and elsewhere (see D.I.

CLAIM TERM	CONSTRUCTION
U.S. Patent No. 10,610,511, claims 1, 12, and 18: “without food”	“the patient has not consumed food within 30 minutes prior to administration of tasimelteon and does not consume food with the administration of tasimelteon” ²
U.S. Patent No. 10,829,465, claim 13: “step (b)”	“the crystallizing step of claim 13”
U.S. Patent No. 10,829,465, claim 13: “assaying the crystallized tasimelteon . . . for the presence of one or both of Impurity 5 . . . and Impurity 6”	“determining whether the crystallized tasimelteon contains one or both of Impurity 5 and Impurity 6” ³
U.S. Patent No. 10,611,744, claim 1: “batch of tasimelteon”	Plain and ordinary meaning; the term does not refer to a batch of tasimelteon drug product. ⁴

143, at B-1) with Defendants at the time and in the papers filed with the Court raising no challenge and reserving no right to appeal. Vanda otherwise takes no position on Defendants’ reservation of rights at this time.

² *See* D.I. 183 at 3 (identifying same construction for term in claims 1 and 6 of U.S. Patent No. 10,376,487).

³ *See* D.I. 183 at 4 (identifying same construction for “analyzing” term in claim 22 of U.S. Patent No. 10,071,977).

⁴ *See* D.I. 105 at 4 (establishing same construction for term in claim 23 of U.S. Patent No. 10,071,977). Vanda accepts that the Court’s construction of “batch of tasimelteon” in U.S. Patent No. 10,071,977 is the law of the case and applies equally to U.S. Patent No. 10,611,744 at issue here. Vanda reserves its rights to appeal that construction, with respect to both patents, at the appropriate time if necessary.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

Karen Jacobs (#2881)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
kjacobs@morrisnichols.com
dfahnestock@morrisnichols.com

*Attorneys for Plaintiff
Vanda Pharmaceuticals Inc.*

OF COUNSEL:

Nicholas Groombridge
Eric Alan Stone
Josephine Young
Daniel J. Klein
Jennifer Rea Deneault
Michael F. Milea
PAUL, WEISS, RIFKIND, WHARTON
& GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

SHAW KELLER LLP

/s/ Karen E. Keller

John W. Shaw (#3362)
Karen E. Keller (#4489)
Nathan R. Hoeschen (#6232)
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com

*Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.*

OF COUNSEL:

J.C. Rozendaal
Deirdre M. Wells
William H. Milliken
STERNE, KESSLER, GOLDSTEIN
& FOX P.L.L.C.
1100 New York Avenue, N.W., Suite 600
Washington, DC 20005
(202) 772-8747

COZEN O'CONNOR

/s/ Thomas Francella

Thomas Francella (#3835)
1201 North Market Street, Suite 1001
Wilmington, DE 19801
(302) 295-2025
tfrancella@cozen.com

*Attorneys for Defendants
Apotex Inc. and Apotex Corp.*

OF COUNSEL:

Barry P. Golob
W. Blake Coblenz
Aaron S. Lukas
COZEN O'CONNOR
1200 Nineteenth Street N.W.
Washington, DC 20036
(202) 912-4800

Keri L. Schaubert
COZEN O'CONNOR
3 WTC, 175 Greenwich Street
55th Floor
New York, NY 10007
(212) 509-9400

PHILLIPS, McLAUGHLIN & HALL, P.A.

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com
dab@pmhdelaw.com

*Attorneys for Defendants
MSN Pharmaceuticals Inc. and
MSN Laboratories Private Limited*

OF COUNSEL:

Kevin E. Warner
Bryce A. Cooper
Reid F. Smith
Elizabeth E. Grden
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
(312) 558-5600

April 29, 2021

SO ORDERED this _____ day of _____, 2021.

United States District Judge